STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Healthcare Quality And Safety Branch

January 15, 2019

Lisa Fucci, Director of Regulatory Compliance
Saint Mary's Hospital
56 Franklin Steet
Waterbury, CT 06706

Dear Ms. Fucci:

Unannounced visits were made to Saint Mary's Hospital commencing on September 25, 2018 and concluding December 6, 2018 by representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting multiple investigations, a licensure and a certification inspection.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

In accordance with Connecticut General Statutes, section 19a-496, upon a finding of noncompliance with such statutes or regulations, the Department shall issue a written notice of noncompliance to the institution. Not later than ten days after such institution receives a notice of noncompliance, the institution shall submit a plan of correction to the Department in response to the items of noncompliance identified in such notice.

The plan of correction is to be submitted to the Department by January 29, 2019.

The plan of correction shall include:

(1) The measures that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance;

(2) the date each such corrective measure or change by the institution is effective;

(3) the institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained; and

(4) the title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction.

The plan of correction shall be deemed to be the institution's representation of compliance with the identified state statutes or regulations identified in the department's notice of noncompliance. Any institution that fails to submit a plan of correction may be subject to disciplinary action.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by January 29, 2019 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

An office conference has been scheduled for February 6, 2019 at 1:00PM in the Facility Licensing and Investigations

DATES OF VISIT: Commencing on September 25, 2018 and Concluding on December 6, 2018

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut. Should you wish to retain legal representation, your attorney may accompany you to this meeting. Please be prepared to discuss those violations identified with an asterisk.

Alternate remedies to violations identified in this letter may be discussed at the office conference. In addition, please be advised that the preparation of a Plan of Correction and/or its acceptance by the Department of Public Health does not limit the Department in terms of other legal remedies, including but not limited to, the issuance of a Statement of Charges or a Summary Suspension Order and it does not preclude resolution of this matter by means of a Consent Order.

Should you have any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Susan Newton, RN, BS
Supervising Nurse Consultant
Facility Licensing and Investigations Section

SHN:mb

Complaint #23916, 23917, 24231, 24249, 24171, 24034, 23738, 23697, 23382, 23182, 22960, 2285, 22817, 22716, 22656, 22624, 22583, 22555, 22367, 22214, 22133, 22034, 21910, 21825, 21777, 21450, 21358, 21203

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2).

DATES OF VISIT: Commencing on September 25, 2018 and Concluding on December 6, 2018

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

1. Based on a review of hospital documentation, a review of policies and procedures, a review of committee meeting minutes and interviews, the hospital failed to comprehensively collect and analyze data for the department of anesthesia, laboratory services and multiple other departments to monitor the effectiveness and safety of services and quality of care. The finding included:
   a. Interview and review of the quality committee minute meetings dated October 2016 to August of 2018 with the Director of Quality on 9/28/18 at 11:00am failed to identify that the department of anesthesia, pharmacy, laboratory services and multiple other departments reported to the quality committee.
   Review of the reporting schedule for year 2018 for the Medical Quality and Safety Committee failed to identify that each department in the hospital was scheduled to report to the Quality Committee at regular intervals. The hospital failed to have a record of the reporting schedule for 2016 or 2017.
   Interview with the Director of Quality on 9/28/18 at 11:00am indicated she was hired in April of 2018 and was not aware that each department was absent from the reporting schedule. Further interview identified that she was not aware that each department would be responsible to identify high risk areas, collect data, analyze the data, take action aimed at performance improvement, track performance to ensure sustainability, and to report the information to the quality committee on a routine basis.
   Interview with the Chief Nursing Officer (CNO) and the Chief Medical Officer (CMO) on 9/26/18 at 4:00 PM indicated they were not aware that each department was not on the 2018 reporting schedule and that each department had not attended the quality meeting routinely to discuss high risk areas in each service line, provide data collection, analysis, and implementation of improvement projects to reflect the betterment of health care outcomes in all areas. Further interview with the CNO and CMO identified they were hired in February of 2018 and indicated the failure to ensure that all components of the quality department were inclusive and comprehensive was likely due to the transition in leadership of the hospital.
   Review of the Performance Improvement Management Plan dated January 2016 directed in part, a continuous improvement strategy that incorporated the review, measurement, assessment, and improvement activities for organization-wide performance to ensure quality service to patients. The plan included the development and deployment of methods to improve organizational areas based on data specific to the department's scope of care. Performance improvement strategies would also be based on measurement and assessment of process outcomes. The quality committee would ensure that process design facilitates current practice and was clinically sound. Furthermore, the committee would ensure the same level of care to all patients through a cross functional review of patient care activities provided by personnel delivering direct care and support services. The committee would assess the departmental performance information as it related to the scope of care and would be responsible to ensure the development and deployment of all performance improvement strategies.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b)

DATES OF VISIT: Commencing on September 25, 2018 and Concluding on December 6, 2018

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Administration (2).

2. Based on review of hospital documentation, a review of policies and procedures, a review of committee meeting minutes and staff interviews, the hospital failed to comprehensively focus on high risk, or problem prone areas and take action at performance improvement activities, measure its success and ensure sustainability for the department of anesthesia, pharmacy, laboratory services and multiple other departments. The finding included:
   a. Interview and review of the quality committee minute meetings dated October 2016 to August of 2018 with the Director of Quality on 9/28/18 at 11:00 am failed to identify that the department of anesthesia, laboratory services and multiple other departments reported to the quality committee.
   Review of the reporting schedule dated 2018 for the Medical Quality and Safety Committee failed to identify that each department in the hospital was scheduled to report to the Quality Committee at regular intervals. The hospital failed to have record of the reporting schedule for 2016 or 2017.
   Further interview with the Director of Quality on 9/28/18 at 11:00am indicated she was hired in April of 2018 and was not aware that each department was absent from the reporting schedule. Moreover, the Director of Quality identified she was not aware that each department would be responsible to identify high risk areas, collect, analyze data, take action aimed at performance improvement, track performance to ensure sustainability and to report the information to quality on a routine basis.
   Interview with the Chief Nursing Officer (CNO) and the Chief Medical Officer (CMO) on 9/26/18 at 4:00 PM indicated they were not aware that each department was not on the 2018 reporting schedule and that each department had not attended the quality meeting routinely to discuss high risk areas in each service line, provide data collection, analysis, and implementation of improvement projects to reflect the betterment of health care outcomes.
   Further interview with the CNO and CMO identified they were hired in February of 2018 and indicated the failure to ensure that all components of the quality department were inclusive and comprehensive was likely due to the transition in leadership of the hospital.
   Review of the Performance Improvement Management Plan dated January 2016 directed in part, a continuous improvement strategy that incorporated the review, measurement, assessment, and improvement activities for organization-wide performance to ensure quality service to patients. The plan included the development and deployment of methods to improve organizational areas based on data specific to the department's scope of care. Performance improvement strategies would be based on measurement and assessment of process outcomes. The quality committee would ensure that process design facilitates current practice and was clinically sound. Furthermore, the committee would ensure the same level of care to all patients through a cross functional review of patient care activities provided by personnel delivering direct care and support services. The committee would assess the departmental performance information as it related to the scope of care and would be responsible to ensure the development and deployment of all performance improvement strategies.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b)

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Administration (2).

3. Based on review of hospital documentation, review of policies and procedures, review of committee meeting minutes and interviews, the hospital failed to develop annual improvement projects for the departments of anesthesia, pharmacy, laboratory including multiple other departments. The finding included:
   a. Interview and review of the quality committee minute meetings dated October 2016 to August of 2018 with the Director of Quality on 9/28/18 at 11:00 AM failed to identify that the department of anesthesia, pharmacy, laboratory services and multiple other departments reported to the quality committee. Further review of the quality committee minute meeting dated October 2016 to August of 2018 failed to identify annual improvement projects. Review of the reporting schedule dated 2018 for the Medical Quality and Safety Committee failed to identify that each department in the hospital was scheduled to report to the Quality Committee at regular intervals. The hospital failed to have record of the reporting schedule for 2016 or 2017.
   Review of the Performance Improvement Management Plan dated January 2016 failed to identify that annual improvement projects were the responsibility of the quality committee. Further interview with the Director of Quality indicated she was hired in April of 2018 and was not aware that each department was absent from the reporting schedule. Moreover, the Director of Quality identified she was not aware that annual improvement projects should have been identified and incorporated into the Performance Improvement Management Plan.
   Interview with the Chief Nursing Officer (CNO) and the Chief Medical Officer (CMO) on 9/26/18 at 4:00 PM indicated they were not aware that each department was not on the 2018 reporting schedule and had not attended the quality meeting routinely to discuss high risk areas in each service line, provide data collection, analysis, and implementation of improvement projects to reflect the betterment of health care outcomes. Additionally, the CNO and CMO were not aware that the annual improvements had not been identified for 2018. Further interview with the CNO and CMO indicated they were hired in February of 2018 and identified the failure to ensure that all components of the quality department were inclusive and comprehensive was likely due to the transition in leadership.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2).

4. Based on review of hospital policies, a review of facility documentation, review of hospital meeting minutes and interviews, the hospital failed to ensure anesthesia, pharmacy, laboratory, and multiple other departments were incorporated in the hospital-wide QAPI (Quality Assurance Performance Improvement) Committee.
   The finding included:

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a. Interview and review of the quality committee minute meetings dated October 2016 to August of 2018 with the Director of Quality on 9/28/18 at 11:00am failed to identify that the department of anesthesia, pharmacy, laboratory services and multiple other departments reported to the quality committee.
Review of the reporting schedule dated 2018 for the Medical Quality and Safety Committee failed to identify that each department in the hospital was scheduled to report to the Quality Committee at regular intervals. Further review identified that the hospital failed to have record of the reporting schedule for 2016 or 2017.
Further interview with the Director of Quality indicated she was hired in April of 2018 and was not aware that each department was absent from the reporting schedule. Moreover, the Director of Quality identified she was not aware that each department would be responsible to identify high risk areas, collect, analyze data, take action aimed at performance improvement, track performance to ensure sustainability and to report the information to quality on a routine basis.
Interview with the Chief Nursing Officer (CNO) and the Chief Medical Officer (CMO) on 9/26/18 at 4:00 pm indicated they were not aware that each department was not on the 2018 reporting schedule and had not attended the quality meeting routinely to discuss high risk areas in each service line, provide data collection, analysis, and implementation of improvement projects to reflect the betterment of health care outcomes. Further interview with the CNO and CMO identified they were hired in February of 2018 and indicated the failure to ensure that all components of the quality department were inclusive and comprehensive was likely due to the transition in leadership.
Review of the Performance Improvement Management Plan dated January 2016 directed in part, a continuous improvement strategy that incorporated the review, measurement, assessment, and improvement activities for organization-wide performance to ensure quality service to patients. The plan included the development and deployment of methods to improve organizational areas based on data specific to the department's scope of care. Performance improvement strategies would be based on measurement and assessment of process outcomes. The quality committee would ensure that process design facilitates current practice and was clinically sound. Furthermore, the committee would ensure the same level of care to all patients through a cross functional review of patient care activities provided by personnel delivering direct care/support services. The committee would assess the departmental performance information as it related to the scope of care and would be responsible to ensure the development and deployment of all performance improvement strategies.
Further review of the Performance Improvement Management Plan dated January 2016 directed that the Quality and Patient Safety Committee would assist the board in overseeing and ensuring the quality of clinical care and patient safety for the hospital. The Board of Directors would maintain ultimate responsibility for the effectiveness of the performance improvement management system.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2).

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5. Based on review of hospital documentation, review of policies and procedures, review of committee meeting minutes and staff interviews, the hospital failed to comprehensively address priorities for improved quality care and determine the number of distinct improvement projects to be conducted annually. The finding included:
   a. Interview and review of the quality committee minute meetings dated October 2016 to August of 2018 with the Director of Quality on 9/28/18 at 11:00 am failed to identify that the department of anesthesia, pharmacy, laboratory services and multiple other departments reported to the quality committee.
   Review of the reporting schedule dated 2018 for the Medical Quality and Safety Committee failed to identify that each department in the hospital was scheduled to report to the Quality Committee at regular intervals.The hospital failed to have record of the reporting schedule for 2016 or 2017. Further review of the quality committee minute meeting dated October 2016 to August of 2018 failed to identify annual improvement projects.
   Review of the Performance Improvement Management Plan dated January 2016 failed to identify that annual improvement projects were part of the responsibility of the quality committee.
   Further interview with the Director of Quality indicated she was hired in April of 2018 and was not aware that each department was absent from the reporting schedule. Moreover, the Director of Quality identified she was not aware that annual improvement projects should have been identified and incorporated into the Performance Improvement Management Plan.
   Interview with the Chief Nursing Officer (CNO) and the Chief Medical Officer (CMO) on 9/26/18 at 4:00 PM indicated they were not aware that each department was not on the 2018 reporting schedule and had not attended the quality meeting routinely to discuss high risk areas in each service line, provide data collection, analysis, and implementation of improvement projects to reflect the betterment of health care outcomes. Additionally, the CNO and CMO were not aware that the annual improvements had not been identified for 2018. Further interview with the CNO and CMO identified they were hired in February of 2018 and indicated the failure to ensure that all components of the quality department were inclusive and comprehensive was likely due to the transition in leadership.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (g) Pharmacy (1)(2)(3)(4) and/or (i) General (6).

6. *Based on observation, a review of facility documentation, interviews, and policy review, the hospital failed to provide the necessary supervision of pharmacy services to ensure that policies and procedures were developed and comprehensive related to the preparation of compounding medications, and/or failed to provide evidence of staff training, and/or failed to ensure a process was in place to monitor adherence to the policies and procedures in accordance with Federal and/or state laws, United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding (USP-797). The findings include:
   a. During a tour of the pharmacy on 10/3/18 with the Department of Consumer Protection

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(DCP), it was noted that multiple compounded medications located in the refrigerator were absent a label that identified beyond use dating (BUD) and/or a multidose vial of Gentamycin was not labeled with the BUD.
Interview with the Director of the Pharmacy on 10/3/18 indicated that the pharmacy staff had been utilizing expiration dates for most sterile compounding preparations that identified a two day expiration date. Subsequent to the surveyor inquiry with the Director of Pharmacy identified that all Compounded Sterile Preparations (CSP's) would be immediately labeled with the appropriate BUD in accordance with USP 797 guidelines.

b. During a tour of the pharmacy on 10/3/18 it was observed that the Pharmaceutical staff and Environmental services failed to wash hands for thirty second up to their elbow.
c. During a tour of the pharmacy on 10/3/18 it was observed that the Pharmaceutical staff and Environmental services failed to clean their fingernails with a nail pick.
d. During a tour of the pharmacy on 10/3/18 it was observed that the Pharmaceutical staff and Environmental services failed to dry their hands with a non-shedding towel.
e. During a tour of the pharmacy on 10/3/18 it was observed that the Pharmacy Technician was wearing makeup.
f. During a tour of the pharmacy on 10/3/18 it was observed that the Pharmacist had exposed skin.
g. During a tour of the pharmacy on 10/3/18 it was observed that Environmental staff failed to wear a gown that provided appropriate coverage.
h. During a tour of the pharmacy on 10/3/18 it was observed that the Pharmacy Technician failed to dispose of gowns and could not identify if the gown was reusable per manufacturers recommendation.
i. During a tour of the pharmacy on 10/3/18 it was observed that Pharmaceutical staff failed to utilize sterile gloves during compounding preparation and failed to don sterile gloves over the isolator gloves.
j. During a tour of the pharmacy on 10/3/18 it was observed that the Environmental and Pharmacy Techician failed to use a waterless based alcohol scrub subsequent to leaving the isolator and prior to resuming compounding.
k. During a tour of the pharmacy on 10/3/18 it was observed that Environmental services and the Pharmacy Technician placed a shoe covers on their feet and failed to step across the line of demarcation in accordance with USP 797.
l. During a tour of the pharmacy on 10/3/18 it was observed that reusuable mop handles were not in original working condition and not labeled.
m. During a tour of the pharmacy on 10/3/18 it was observed that the Pharmaceutical staff and Environmental Services failed to differentiate mini-mop handles used for the hazardous versus the non-hazardous isolator.
n. During a tour of the pharmacy on 10/3/18 it was observed the Environmental staff failed to document the mixing and diluting of cleaning and sanitizing agents via a log.
o. During a tour of the pharmacy on 10/3/18 it was observed that all Pharmaceutical Techniciaan's failed to appropriately label the sterile isopropyl alcohol when it was opened or the expiration date.
p. During a tour of the pharmacy on 10/3/18 it was observed that the Environmental staff failed to document that the the cart utilized in the segregated compounding area was cleaned

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daily.

q. During a tour of the pharmacy on 10/3/18 it was observed that a fatigue mat was utilized however the documentation failed to identify how it was cleaned and/or appropriate for use.
r. During a tour of the pharmacy on 10/3/18 it was observed that a tacky mat was utilized outside of the segregated compounding area and failed to be located directly in front of the entry door.
s. During a tour of the pharmacy and a review of the manufacturers guidelines for cleaning of the isolators on 10/3/18 it was identified that the dwell time should be ten minutes however, an observation indicated the drying time in parts of the isolator was ninety seconds, and the technician failed to rewet the surfaces to ensure the appropriate dwell time.
t. During a tour of the pharmacy on 10/3/18 it was observed the facility failed to have non-permeable surfaces to ensure appropriate cleaning ie. wood doors, particle boards under counters, walls and ceilings.
u. During a tour of the pharmacy on 10/3/18 it was observed in the sterile compounding room that the facility failed to ensure walls were painted with epoxy based paint and bare wood was observed.
v. During a tour of the pharmacy on 10/3/18 it was observe in the sterile compounding room that the facility failed to ensure that light fixtures were sealed.
w. During a tour of the pharmacy on 10/3/18 it was observed that the segregated compounding area was overstocked with unused sharps containers and a large supply of isolator gloves.
x. Review of the hospital documentation failed to identify that agar plates were utilized for fingertip testing and that documentation lacked the results, hand designation, the dates, incubation temperature, signature of observer and that daily checking was conducted.
y. Review of the hospital documentation failed to identify that media fill tests final results were documented as pass or fail. The documentation failed to include the incubation time or temperature, and/or the media testing procedures did not include the fill volume, inspection of filled units, interpretation of results, and action levels with the correct actions required.
z. Review of the hospital documentation failed to identify that compounding and environmental service staff have documented competencies for gowning and handwashing.
aa. Review of the hospital documentation failed to identify a risk acknowledgement and/or that compounding personnel had hazardous didactic training and/or that observational assessments were documented.
bb. Review of the hospital documentation failed to identify that the compounding containment isolator failed to have documentation that indicated the room in which it is located maintained a minimum of twelve air exchanges per hour.
cc. Review of the hospital documentation failed to indicate the volume of the primary engineering control (PEC) when obtaining air samples.
dd. Review of the pharmacies standard operating procedures (SOP) identified the hospital failed to comprehensively address SOP's for the clean room regarding cleaning and environmental testing.
ee. Review of the pharmacies standard operating procedures identified the hospital failed to address that all sterile compounds would be identified as hazardous.
ff. Review of the pharmacies standard operating procedures identified the hospital failed to address if gowns utilized in the sterile compounding room were reusable per manufacturers

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recommendations and if they were not disposable, where and how would they be stored.

gg. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP regarding how frequency the tacky mat would be changed or replaced.

hh. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP that directed how frequent the tacky matt would be changed or replaced and/or its appropriate location.

ii. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP prohibiting personnel from entering the compounding area and/or clean room if they have a sunburn, weepin sores, conjunctivitis or an active respiratory infection.

jj. Review of the pharmacies standard operating procedures identified the hospital failed to have an SOP that directed all personnel in the compounding area are required to remove all jewelry and makeup.

kk. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP that prohibited all personnel from wearing artificial nails or extenders, and that required staff to keep natural nails neat and trimmed.

ll. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP regarding how frequency the fatigue mat would be changed or replaced.

mm. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP regarding how every CSP would be visually inspected for the presence of particulate matter, evidence of incompatibility or other issues.

nn. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP that directed single dose containers, bags, bottles, syringes or vials that were opened or punctured in worse than ISO Class 5 air used within one hour and the remaining contents discarded and/or how are they identified for expiration.

oo. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP that directed single dose vials exposed to ISO 5 air or cleaner used within six hours of the initial puncture and any remaining contents discarded and/or how are they identified for expiration.

pp. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP that directed multiple dose vials assigned a BUD of 28 days or the manufacturers specific BUD, (whichever was less) after the initial entry or puncture and/or how are multi-dose vials identified for expiration after they have been opened or punctured.

qq. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP for in process checks performed by a pharmacist and to ensure that procedures were followed.

rr. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP that directed if a CACI (compounding aseptic container isolator) was used, the room in which it was located needed to be certified to a minimum or 12 ACPH (air change per hour).

ss. Review of the pharmacies standard operating procedures identified the hospital failed to have a SOP that directed all compounding staff would have passed an initial and subsequent annual competency assessments of aseptic compounding skills including handling hazardous drugs and that all pharmacists and technicians performing compounding using hazardous drugs were appropriately trained in the safe handling, garbing, cleaning, and

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disinfecting procedures and waste disposal of hazardous drugs and materials.
Interview with the Director of the Pharmacy on 10/4/18 at 2:00 PM indicated although the staff was trained in USP 797 guidelines he was unaware of the garbing procedures as this pharmacy had isolators and not a "clean room". Further interview with the Director of Pharmacy identified he did not conduct surveillance of garbing, handwashing or cleaning therefore was unaware that the USP 797 guidelines were not performed in accordance with the regulations. Furthermore, the Director was unaware that the hospital's standard operating procedures were not comprehensive.
Interview with the Infection Control Nurse on 10/4/18 at 2:15 PM identified she was new in the role of infection control and although she was aware the compounding room was a high risk area she had not initiated surveillance rounds to ensure garbing, handwashing, cleaning and that all infection control practices were maintained in the aseptic area of the pharmacy.
Interview with the Director of Environmental Services on 10/4/18 at 1:20 PM identified he was not aware that a mixing log was needed to verify the appropriate cleaning solutions and their amounts. Additionally, the Director of Environmental Services indicated the Environmental staff was trained on gowning, handwashing and cleaning of the compounding area by the operations manager however documentation of the training was not available.
The job description of the pharmacy director in part identified that he/she would oversee the management of the entire scope of the pharmacy department. The director plans, organizes, staffs, directs, controls, problem-solves, develops staff, reinforces performance and facilitates the work of others. Furthermore, the director of the pharmacy updates departmental policies and procedures, ensures departmental compliance with intravenous compounding and regulatory standards.
An immediate plan of action dated 10/4/18 directed that a policy would be created for Beyond Use Dating for all CSP's. Expiration dates would no longer be used. All new CSP's would immediately be labeled with a BUD and all other CSP's with expiration dates would be disposed of. In addition, compounding staff would be trained immediately and/or prior to the next working shift by the pharmacy manager.
The immediate plan of action directed that a policy would be written for proper hand hygiene for entry into the compounding area including the use of sterile gloves, lint free towels, the use of full gown coverage and garbing in relationship to the line of demarcation. In addition, training would be completed prior to the next working shift by the pharmacy manager and by the infection control nurse. Additionally, the fatigue mat, extra sharp containers, and clutter was removed from the compounding area. Moreover the staff would be immediately trained when cleaning the isolators to ensure a dwell time of ten minutes until an alternate cleaning product could be obtained. This training would be conducted by the pharmacy manager prior to the next working shift.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6).

7. *Based on the hospital's medical record review, facility policies, documentation and staff interviews, the laboratory director failed to ensure proper oversight of testing personnel to

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ensure laboratory testing personnel report critical value test results according to established policies and procedures and maintain competency to report critical tests results promptly and proficiently in accordance with the Clinical Laboratory Improvement Act (CLIA) requirements. The findings include:

a. Review of hospital root cause analysis and action plan on 9/26/18 for testing performed Sunday 8/5/18 between 3:23PM - 6:57PM, Laboratory Technician#1 (LT) questioned Patient #1's abnormally high potassium (K) result of 9.0 mEq/L(normal range for K is 3.5 - 5.1 mEq/L). The K test was automatically repeated by the chemistry analyzer to auto recheck the validity of the K result. The auto recheck confirmed an abnormally high K result of 9.1 mEq/L. LT #1 cancelled the Basic Metabolic Panel (BMP) order without recording it in the laboratory information system (EPIC) and did not verbally relay the critical result to the unit coordinator (UC), and only requested a redraw. The Surgical Intern realized the first BMP was cancelled at 4:55PM and ordered a 2nd BMP test at 5:12PM which was received in the lab at 5:56PM. At 6:21PM the patient coded and the Registered Nurse (RN) immediately called the lab to inquire about BMP results. LT#1 reported the only available test result, being Sodium at 134(normal range is 136-145mEq/L). The RN heard "K 3.4" with no read back to verify the accuracy of the result, which was reported to the code team. At 6:51PM LT #1 called the UC to report the K result of 9.5. Patient #1 was pronounced dead at 6:55PM.

   1. Laboratory Technician #1 (LT) failed to follow laboratory procedures for reporting of critical result values. The laboratory Evaluation of Patient Data policy and procedure (number Chem 22.0) approved on 10/12/17 states a "Fail verify" result that has been determined to be critical will immediately be called to the healthcare provider and to follow the laboratory procedure of documentation.
      For an "Absurd Value" an absurd message will be sent when a result is entered that has been defined according to the Min/Max value to be non-compatible. The result must be rerun and verified before being accepted.
   2. Laboratory Technician #1 (LT) failed to follow the hospital Quality Assurance Performance Improvement (QAPI) procedures for reporting critical values. The hospital policy "Critical Laboratory Test Results Warranting MD Alerts" effective November 2014 which states "The following test results warrant immediate notification (regardless of the delta checks) to the physician, nurse, or other appropriate health professional within thirty minutes of being completed. After each result has been rechecked by a technologist, he/she will document in the LIS and on the department copy of the report (if applicable) the name of the person(s) notified, date and time called, verification of "read-back" results and the initials of the person making the call. The initials indicate that the person receiving the critical results have read back to the caller the patient's full name and complete results." The above procedure also states that all potassium (K) results over 6.0 mEq/L are critical and the physician, nurse, or other appropriate health professional must be notified.
   3. Laboratory Technician #1written statement to the Technical Supervisor (undated) identified Patient #1 was admitted to the emergency room (ER) on 8/5/18. A basic metabolic panel (BMP) along with other tests were ordered and specimen was sent to the lab at 3:59PM on 8/5/18 for testing. A critical 9.1 mEq/L potassium (K) high result

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value was obtained. Laboratory Technician #1called the ER and directed the Unit Coordinator to recollect the sample due to the sample being questionable and cancelled the BMP test. The critical potassium result value of 9.1 mEq/l was never reported to the Unit Coordinator or entered in the LIS (Laboratory Information System).

4. Review of the patient test report on 9/26/18 for the above specimen sample number X125502 revealed the BMP was deleted with a comment which stated "specimen unsuitable. Please re-order or resubmit. IV fluid contamination." The laboratory information system, (Sunquest), audit system revealed the identification number for the Laboratory Technician who entered the above comment for sample number X125502 was Laboratory Technician #1.
5. Review of the state survey telephone interview with Laboratory Technician #1 on 9/11/18 at 7:55 PM identified the ER was notified on 8/5/18 at 4:56 PM, the test result was questionable and to redraw the patient with no mention of the critical K result. Laboratory Technician #1 further identified he/she wasn't properly trained, was not shown laboratory policies or asked to sign any policies, the critical laboratory procedure was not clear on how to report questionable critical values and that no one had observed Laboratory Technician #1 resulting or reporting critical value results.
6. Review of Laboratory Technician #1 training documentation on 9/26/18 failed to provide evidence of direct observation of reporting critical values however, Laboratory Technician #1 checked the box on the training form that he/she fully understood and felt competent to perform critical Values/Documentation for the Beckman Coulter AU5800 instrument on 5/8/18. The Technical Supervisor signed off Laboratory Technician #1 was fully trained on 5/12/18.
7. Review on 9/26/18 of the state surveyor's interview with the Technical Supervisor on 9/6/18 at 9:45 AM identified Laboratory Technician # 1 failed to follow laboratory procedures for reporting of critical value results. Laboratory Technician # 1 was hired on 3/12/18 and signed training documentation on 5/8/18 indicating he/she was fully competent to perform and report critical value results. Technical Supervisor signed Laboratory Technician #1 training documentation on 5/12/18 and identified once the Technical supervisor signs training documents, staff are considered competent to perform those duties.
8. Interview with the Laboratory Director on 9/26/18 at 4:00PM identified Laboratory Technician #1 failed to follow the hospital QAPI and laboratory policies and procedures for the reporting of critical values and that he/she relies on the Technical Supervisor to train, evaluate and monitor laboratory technicians for pre-analytical, analytical and post-analytical testing in the laboratory.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (i) General (6).

8. *Based on staff interviews and a review of the hospital's policies and procedures, the hospital failed to h
   a. Review of the clinical record identified Patient #1 was admitted to the hospital on 7/31/18 with cholecystitis and underwent a laparoscopic cholecystectomy under general anesthesia on 8/1/18. Interview and review of the surgical report with

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(Certified Registered Nurse Anesthetists) CRNA #1 on 9/25/18 at 2:00 PM identified Patient #1 entered the operating room on 8/1/18 at 12:04 PM. CRNA #1 and MD #1 were present. Anesthesia induction commenced at 12:14 PM with medications that included Versed, Propofol, Fentanyl, and Rocuronium. Patient #1 was intubated at 12:16 PM. CRNA #1 indicated the intubation was difficult with tightness identified around the intubation tube that required further assessments and repositioning. After the intubation was completed by MD #1, who was the anesthesiologist, MD #1 left the room. Shortly after MD #1 left the room, elevated peak pressures were noted, the endotracheal tube (ET) was reevaluated and ventilation settings were adjusted. A surgical time out was then conducted. CRNA #1 indicated she stopped what she was doing to participate in the time out and to verify if antibiotics were administered, as she had not reviewed the medical record prior to the initiation of the case. The surgical incision was made at 12:26 PM. Subsequent to the surgical incision, CRNA #1 identified she assessed the patient's airway with a laryngoscope to ensure placement of the ET tube. Patient #1's blood pressure and heartrate were elevated which was thought to be related to sympathetic stimulus, therefore, Propofol and Diludid were administered. CRNA #1 indicated almost immediately thereafter it was identified that Patient #1 was breathing over the ventilator which triggered CRNA #1 to check the vaporizer. CRNA #1 realized the Sevoflourine gas had not been turned on for approximately nineteen minutes from the time of the incision. CRNA #1 immediately administered the Sevoflurane (inhalation anesthetic) for the remainder of the case. Subsequent to the procedure, the patient was able to verbalize explicit details of the case and complained of pain during part of the procedure.

Further interview with CRNA #1 indicated she was not originally scheduled to provide anesthesia in this case. CRNA #1 identified she had not set up the room and did not have time to review the medical record as was her routine practice. CRNA #1 indicated she should have stopped the line prior to the surgical time out and asked for MD #1 to return to the room to assist in troubleshooting the ventilator, ensure the ET tube placement and overall assessment of the patient prior to the surgical incision.

Interview with MD # 1 on 9/25/18 at 3:00 PM identified he was present for the induction and intubation of Patient #1 however, did not ensure that the Sevoflurane was on prior to leaving the room.

Interview with the Chief of Anesthesia on 9/25/18 at 1:00 PM identified although the CRNA's administered the Sevoflurane, it was the responsibility of the physician to ensure the Sevoflurane was turned on prior to leaving the room. Further interview and review of the hospital policy entitled Guidelines for Administration of Anesthesia with the Chief of Anesthesia directed in part that an Anesthesiologist or CRNA would be present at the induction of each anesthetic and that all anesthetics initiated by a member of the Department of Anesthesia required the presence of an attending anesthesiologist throughout the administration of general anesthesia. The Chief of Anesthesia indicated the policy was inaccurate and would be changed to identify that an attending anesthesiologist would be present for the induction of each

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anesthetic when the case was assigned to a CRNA and that either an anesthesiologist or CRNA would be present throughout the duration of general anesthesia. Subsequent to the incident education was provided to all attending anesthesiologists that indicated the anesthesiologist would be responsible to ensure that he/she was present for induction, intubation, and to verify the anesthetic gas had been turned on prior to leaving the room. The attestation would be recorded in each clinical record.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (i) General (6).

9. *Based on a clinical record review, staff interviews and a review of hospital documentation for one of ten administering inhalational anesthetic throughout the surgical procedure which subsequently rendered intraoperative awareness and discomfort to the patient. The finding included:

a. Review of the clinical record identified Patient #1 was admitted to the hospital on 7/31/18 with cholecystitis and underwent a laparoscopic cholecystectomy under general anesthesia on 8/1/18. Interview and review of the surgical report with CRNA #1 on 9/25/18 at 2:00 PM identified Patient #1 entered the operating room on 8/1/18 at 12:04 PM. CRNA #1 and MD #1 were present. Anesthesia induction commenced at 12:14 PM with medications that included Versed, Propofol, Fentanyl, and Rocuronium. Patient #1 was intubated at 12:16 PM. CRNA #1 indicated the intubation was difficult with tightness identified around the intubation tube that required further assessments and repositioning. After the intubation was completed MD #1, who was the anesthesiologist, left the room. Shortly after MD #1 left the room elevated peak pressures were noted, the endotracheal tube (ET) was reevaluated and ventilation settings were adjusted. A surgical time out was then conducted. CRNA #1 indicated she stopped what she was doing to participate in the time out and to verify if antibiotics were administered, as she had not reviewed the medical record prior to the initiation of the case. The surgical incision was made at 12:26 PM. Subsequent to the surgical incision CRNA #1 identified she assessed the patient's airway with a laryngoscope to ensure placement of the ET tube. Patient #1's blood pressure and heartrate were elevated which was thought to be a result of sympathetic stimulus, therefore, Propofol and Diludid were administered. CRNA #1 indicated almost immediately thereafter, it was identified that Patient #1 was breathing over the ventilator which triggered CRNA #1 to check the vaporizer. CRNA #1 realized the Sevoflourine gas had not been turned on for approximately nineteen minutes from the time of the incision. CRNA #1 immediately administered the Sevoflurane for the remainder of the case. Subsequent to the procedure the patient was able to verbalize explicit details of the case and complained of pain during part of the procedure. Further interview with CRNA #1 indicated she was not originally scheduled to provide anesthesia in this case. CRNA #1 identified she had not set up the room, and did not have time to review the medical record as was her rountine practice. CRNA #1 indicated she should have stopped the line prior to the surgical time out and asked for MD #1 to return to the room to assist in troubleshooting the ventilator, ensure the ET tube placement and overall assessment of the patient prior to the surgical incision.
Interview with MD #1 on 9/25/18 at 3:00 PM identified he was present for the induction and

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intubation of Patient #1 however did not ensure that the Sevoflurane was on prior to leaving the room.
Interview with the Chief of Anesthesia on 9/25/18 at 1:00 PM identified although the CRNA's administered the Sevoflurane it was the responsibility of the physician to ensure the Sevoflurane was turned on prior to leaving the room.
Subsequent to the incident, education was provided to all attending anesthesiologists that indicated that the anesthesiologist would be responsible to ensure that he/she was present for induction, intubation, and to verify the anesthetic gas had been turned on prior to leaving the room. The attestation would be recorded in each clinical record.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (i) General (6).

10. Based on a review of facility documentation, interviews and policy review, the facility failed to ensure that quality services were rendered by a contracted service. The findings include the following:

a. Review of the Reverse Osmosis (RO) logs for RO #6 for the month of October indicated that on 10/12/18, RN #109 documented that the Chlorine level was 0.2 parts per million (normal less than 0.1 ppm) at 7:40 AM and again at 2:55 PM. Review of the log and interview with the Clinical Service Specialist (CSS) on 11/15/18 at 9:30 AM stated that RN #109 incorrectly documented the results and should have been 0.02 ppm. The CSS identified that if the result was 0.2 ppm, patients would have experienced an adverse outcome and no patients have. Although the CSS stated she reviews the logs, the error was not identfied until the surveyor inquired about the abnormal results.
b. Review of training education failed to reflect that RN #109 had been educated on water testing. Interview with the Manager on 11/15/18 at 10:00 AM indicated RN #109 was an orientee and had not completed water monitoring education.
c. Review of the reverse osmosis logs for machine #7 for the period of 10/1/18 through 10/26/18 indicated that the normal parameters for RO pressures was 180-200 PSI. Review of the log indicated results of not applicable (n/a) and/or, 170 psi and values 1000-1290. Review of the log with the Biomedical Manager indicated that machine #7 does not have the capability to display the RO pressures and that the log being used was incorrect and it was unclear where staff could be getting the results documented. Subsequent to inquiry, the log was switched to reflect the appropriate monitoring that is required.
Review of the policy indicated only teammates who have been trained to perform the observations and testing required will be permitted to test and document their findings on a water treatment log. On 11/15/19, the hospital provided the Department with an immediate action plan that identfied all staff will be reeducated on water testing and documentation of logs (RO start-up log).

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b)

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Administration (2) and/or (i) General (6).

11. *Based on observations, documentation review and interviews, the hospital failed to ensure that the psychiatric environment was monitored to ensure patient safety while identified ligature risks were present in the environment. The findings include:

a. Tour of the in-patient psychiatric unit was conducted on 11/8/18 at 10:00 AM. Observations identified 3 medical beds with cranks and side rails in use and 8 patient bathroom doors with hinges not designed for the psychiatric environment, and posed a ligature risk.
The hospital's ligature risk prevention project documentation updated on 11/5/18 was reviewed with the VP of Administration and COO on 11/8/18. The project documentation identified in part that the psychiatric unit had bathroom door hinges that required remediation. It was identified that replacement hinges were on back order from the manufacturer.
Interview with MHW #1 on 11/8/18 at 10:20 AM identified that she was not aware of which bedrooms on the unit had bathrooms with hinges that posed a ligature risk.
Interview with the Director of Psychiatry on 11/8/18 at 10:25 AM identified that he was not aware of which bedrooms on the unit had bathrooms with hinges that posed a ligature risk, and was unaware of which patient bedrooms had medical beds with cranks and side rails. The Director identified that Staff monitored patients by conducting routine every 15 minutes checks and if a patient was experiencing suicidal ideations, he/she would be moved to a room close to the nurses' station. The Director identified that there was no additional safety monitoring for ligature risks in the psychiatric environment.
Subsequently, the hospital developed an environmental monitoring plan to ensure the safety of patients while ligature risks existed on the psychiatric unit.
On 11/5/18 at the time of the tour, the unit census was 12 and there were no patients with current suicidal ideations.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical Staff (2)(B) and/or (e) Nursing Service (1).

12. Based on clinical record review, interviews and policy review for 1 of 3 sampled patients (Patient #164) reviewed for restraint use, the facility failed to discontinue the use of restraints when the resident stopped exhibiting the behavior. The findings include:

a. Patient #164 was admitted on 7/7/18 due to mood liability after a discontinuation of medications and paranoia. Nursing progress notes dated 7/8/18 at 1:30AM identified Patient #164 was increasing psychotic, loud screaming, darting in and out of patient rooms, disoriented, and multiple attempts to hit staff. The note identified the physician was made aware and directed to place the patient in 4 point restraints, STAT medications were administered and the restraint protocol was initiated. Review of the non-violent restraint order dated 7/8/18 at 1:41AM identified physical restraints is medically necessary to maintain patient safety. Review of the restraint monitoring form dated 7/8/18 at 1:30AM identified the patient was in four (4) point restraints from 1:30AM through 5:45AM (a total of 4 hours and 15 minutes). The nursing staff failed to document the patient's assessed

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behaviors on the monitoring form every fifteen minutes from 1:45AM until 3:00AM (a total of 1 hour and 15 minutes). Additionally, from 3:00AM through 5:45AM staff failed to assess/document behaviors necessitating the continued use of the 4 point restraints.
Interview and review of Patient #164 clinical record with the VP of Behavioral Health on 11/15/18 at 11:00AM failed to identify that behaviors were assessed/documented from 1:45AM until 3:00AM, and should have been. Interview with the Director of Regulatory Affairs stated that per policy the behaviors the patient is exhibiting at the time of assessment need to be descriptive to identify the appropriate use of 4 point restraints.
Facility policy for restraints identified the use of restraints should be frequently evaluated and ended at the earliest possible time based on the assessment of the patients compliance with the established behavioral criteria and reevaluation of the patients condition.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical Staff (2)(B) and/or (e) Nursing Service (1).

13. Based on clinical record review, interviews and policy review for 1 of 3 sampled patients (Patient # 164) reviewed for restraint use, the facility failed to identify behaviors that would support the use of continued restraint use. The findings include:

a. Patient #164 was admitted on 7/7/18 due to mood liability after a discontinuation of medications and paranoia. Nursing progress notes dated 7/8/18 at 1:30AM identified Patient #164 was increasing psychotic, loud screaming, darting in and out of patient rooms, disoriented, and multiple attempts to hit staff. The note identified the physician was made aware and directed to place the patient in 4 point restraints, STAT medications were administered and the restraint protocol was initiated. Review of the non-violent restraint order dated 7/8/18 at 1:41AM identified physical restraints is medically necessary to maintain patient safety. Review of the restraint monitoring form dated 7/8/18 at 1:30AM identified the patient was in four (4) point restraints from 1:30AM through 5:45AM (a total of 4 hours and 15 minutes). The nursing staff failed to document the patient's assessed behaviors on the monitoring form every fifteen minutes from 1:45AM until 3:00AM (a total of 1 hour and 15 minutes). Additionally, from 3:00AM through 5:45AM staff failed to assess/document behaviors necessitating the continued use of the 4 point restraints.
Interview and review of Patient # 164 clinical record with the VP of Behavioral Health on 11/15/18 at 11:00AM failed to identify that behaviors were assessed/documented from 1:45AM until 3:00AM, and should have been. Interview with the Director of Regulatory Affairs stated that per policy the behaviors the patient is exhibiting at the time of assessment need to be descriptive to identify the appropriate use of 4 point restraints.
Facility policy for restraints identified the patient is checked every fifteen (15) minutes by qualified staff whether the patient continues to exhibit the behavior indicating a need for a restraint.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2)(B) and/or (e) Nursing Service (1) and/or (i) General (6).

14. *Based on clinical record review, review of hospital policies and interviews with staff

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for 3 of 6 patients undergoing procedures (Patients #120, 121 & 122) the hospital failed to ensure that a time-out was performed accurately resulting in a wrong site biopsy and/or failed to ensure that procedural objects were accounted for resulting in retained objects. The findings include:

a. Patient #120 was admitted on 9/7/17 for an ultrasound-guided left thyroid node biopsy. According to the procedural note, the correct side, site and patient position were verified. Following the time-out MD#106 performed a right thyroid node biopsy in error. Patient #120 was informed of the error and the left node biopsy was then performed. Interview with MD #106 on 11/16/18 at 9:30 AM identified that he was aware that the procedure was to be done on the left side, he performed the procedure on the right side in error.
Interview with the Quality Manager on 11/16/18 at 9:20 AM, review of the hospital's time-out policy and review of the hospital's corrective action plan identified that despite performing the time-out, MD #106 performed the procedure on the incorrect site. Following this incident, staff were re-educated on the time-out policy.

b. Patient #121 was admitted on 9/21/18 and underwent an open ventral hernia repair. Prior to leaving the operating room, a urinary catheter was inserted by RN #101. The patient was discharged home on 9/24/18. On post-operative day #5 Patient #121 identified having pelvic pain, odor and a foreign body was found in the patient's vagina. Patient #121 notified the physician who identified that an image of the foreign body was that of a perineal swap stick used during the insertion of the urinary catheter on 9/21/18.
Interview with RN #101 on 11/15/18 at 10:05 AM identified that the perineal swab stick was inserted into the patient's vagina to use as a guide for the urinary catheter insertion. RN #1 identified that it was a practice learned in nursing school. RN #101 identified that she no longer uses this practice when inserting urinary catheters.
Interview with Quality Staff #1 on 11/15/18 at 11:15 AM, review of the hospital's urinary catheter insertion policy and review of the hospital's corrective action plan identified that RN #101 did not follow the hospital policy for urinary catheter insertion and the swab stick should not have been inserted in the vagina. Following this incident, staff were re-educated on the urinary catheter insertion policy.

c. Patient #122 was admitted on 5/22/18 with a diagnosis of sigmoid colon adenocarcinoma and underwent an open low anterior resection and lysis of adhesions. According to the surgical record, all sponge counts were correct at the conclusion of the surgery. Patient #122's post-operative stay was uncomplicated and was discharged on 5/30/18. Patient #122 returned to the hospital on 8/31/18 after experiencing a lump on the abdomen that was identified as a foreign body. The foreign body was surgically removed and identified as a retained surgical sponge.
Interview with MD #105 on 11/15/18 at identified that at the conclusion of Patient #122's surgery counts were verified as correct twice and he had no reason to suspect otherwise.
Interview with Quality Staff #1 on 11/15/18 at 11:00 AM, review of the hospital's sponge count policy and review of the hospital's corrective action plan identified that despite performing and documenting that sponge counts were correct, a sponge was retained. Following this incident, staff were re-educated on the surgical count process.

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15. *Based on clinical record review, interview and policy review for 1 of 4 patients (Patient #118) the facility failed to ensure that a patient did not receive a medication that he/she had a documented allergy to. The findings include the following:

a. Patient #118 was admitted on 2/19/17 at 2:16 PM with a urinary tract infection. The patient had a history of seizure disorder, cerebral palsy and generalized epileptic syndrome. The nursing note at 7:03 PM indicated that an allergy band was in place. Review of the record with the quality coordinator on 11/14/18 at 1:30 PM indicated that the record reflected that the patient had an allergy to Rocephin.
The record indicated that on 2/19/17 at 9:35 PM MD #107 directed Ceftriaxone 1 gram intravenous times 1, which was administered as directed. A note at 9:45 PM indicated that the patient had an allergic reaction to the Ceftriaxone and had swelling to lips and eyes. The patient was given stat Benadryl and Epinephrine with good effect. The note indicted that the patient did have a documented allergy in the chart.
Interview with the Quality Coordinator in 11/14/18 at 1:30 PM indicated that the allergy was documented in the computer by the triage nurse however was not confirmed. This missing step resulted in the allergy not being linked in the system to identify drug interactions/allergy's. The Quality Coordinator indicated that the allergy was still visible on the home page of the computerized medical record screen.
Following the incident, staff were reeducated and quality monitoring was initiated. In addition, the hospital had changed to a new computer system. MD #107 was unavailable for interview.
The facility failed to ensure that MD# 107 reviewed the patient’s allergies prior to ordering a medication and/or that RN #107 reviewed the patient’s allergies prior to the administration of the medication.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical Staff (2)(B) and/or (d) Medical Records (3).

16. Based on clinical record review, interview and policy review for one patient (Patient #107) the facility failed to ensure that a physician assessment was conducted and/or documented. The findings include the following:

a. Patient #107 was admitted on 4/11/17 for a laparoscopic cholecystectomy. A nursing pre-operative assessment identified a blood pressure of 129/76. A preoperative anesthesia assessment identified the patient's blood pressure as 129/72 at 7:15 AM. The patient arrived in PACU at 8:36 AM with a pain scale of 0/10 (10 worst) and a pain of 10/10 at 8:56 AM. Patient #107 received IV anxiolytic and pain medications. Pain at 9:35 was 4/10 and at 10:42 AM was 10/10.
Review of the anesthesia peripheral nerve block procedural note indicated that a TAP block was completed at 10:35 AM for post-operative analgesia. The anesthesia record identified the patient's blood pressure was 93/59, heart rate was 68, the patient was sedated, following

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commands, stable and tolerated the procedure well. Pain score was 3/10 post procedure at 10:46 AM.

Nursing notes dated 4/11/17 at 10:56 AM identified that Patient #107 was fully awake, out of bed to the bathroom, felt dizzy and faint, and had a blood pressure of 77/44. The physician was notified and 1 liter of lactated ringers was administered. A blood pressure recheck was 96/53. Patient stated he/she felt better with no further dizziness or feeling faint.

Review of nursing post-operative vital signs indicated that the patient's BP remained at "+/- 20 pre-op" or within 20mm Hg of pre-anesthetic systolic level for a high of 149 to a low of 109 at 10:00 and 10:56 despite documented blood pressures of 93/59 and 96/53 respectively.

According to a nurses note dated 4/11/17 at 10:48 AM a physician was in to assess the patient. However, the clinical record failed to reflect a documented assessment by the physician.

Patient #107 was discharged per post-anesthesia protocol at 2:00 PM with discharge instructions.

Interview with the Quality Specialist on 11/16/18 at 10:00 AM indicated that when the case was reviewed it was determined that the surgical resident was notified of the patients dropping blood pressure, saw the patient, ordered IV fluids and asked to be called after the fluids were administered however failed to write a note. Review of the medical staff bylaws indicated that progress notes content shall be sufficient information to permit continuity of care.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (6).

17. *Based on clinical record review, review of hospital policies and interviews with staff for 1 of 6 patients undergoing procedures (Patients #121) the hospital failed to ensure that nursing staff performed a urinary catheterazation per policy and failed to ensure all supplies were accounted for resulting in a retained object. The findings include:

a. Patient #121 was admitted on 9/21/18 and underwent an open ventral hernia repair. Prior to leaving the operating room, a urinary catheter was inserted by RN #101. The patient was discharged home on 9/24/18. On post-operative day #5 Patient #121 identified having pelvic pain, odor and a foreign body was found in the patient's vagina. Patient #121 notified the physician who identified that an image of the foreign body was that of a perineal swap stick used during the insertion of the urinary catheter on 9/21/18.

Interview with RN #101 on 11/15/18 at 10:05 AM identified that the perineal swab stick was inserted into the patient's vagina to use as a guide for the urinary catheter insertion. RN #1 identified that it was a practice learned in nursing school. RN #101 identified that she no longer uses this practice when inserting urinary catheters.

Interview with Quality Staff #1 on 11/15/18 at 11:15 AM, review of the hospital's urinary catheter insertion policy and review of the hospital's corrective action plan identified that RN #101 did not follow the hospital policy for urinary catheter insertion and the swab stick should not have been inserted in the vagina. Following this incident, staff were re-educated on the urinary catheter insertion policy.

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18. Based on clinical record review, interview and review of the guidelines for 1 of 3 patients (Patient #131) reviewed the facility failed to ensure that CIWA documentation was completed correctly. The findings include the following:

a. Patient #131 was admitted on 11/6/18 with alcohol abuse, pancreatitis and suicidal ideation. The record indicated that the physician directed that the patient was to be monitored via the CIWA protocol. Review of the monitoring indicated that on 11/7/18 at 8:00 AM the patient was scored at 8. The patient was next assessed at 5:40 PM, when the patient was assessed at a 15. The guidelines indicated that the patient should be assessed every four hours for a score of 8-15.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1).

19. Based on clinical record review and interview the facility failed to ensure that daily weights were monitored. The finding includes the following:

a. Patient #132 was admitted on 11/3/18 with congestive heart failure, and the physician orders directed daily weights. Review of the clinical record with the Manager on 11/13/18 at 10:30 AM indicated that daily weights were completed on 11/3/18 and 11/5/18. The record failed to reflect that daily weights were completed.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (d) Medical Records (3) and/or (e) Nursing Service (1) and/or (i) General (6).

20. *Based on clinical record review, interview and policy review the facility failed to ensure that 1 of 6 post-operative patients were monitored for pain and/or stability. The findings include the following:

Patient #107 was admitted on 4/11/17 at 12:30 PM for a laporscopic cholecystectomy. Review of the anesthesia peripheral nerve block procedural note indicated that a TAP block was performed at 10:18 AM and completed at 10:35 AM.

a. Review of the post -operative vital signs indicated that the patient's BP pre procedure was 148/100. During the peocedure that patients BP's were was 112-120 /70-80's. The record indicated that at 10:25 AM the patient's BP was 120/76. Review of the clinical record indicated that the patient arrived in same day surgery at approximately 10:56 AM on 4/11/17, the patient had a BP of 94/54, pain level of 5 and was fully awake. The record indicated that Percocet 1 tablet was adminsitered at 11:00 AM. The record failed reflect further monitoring of the patients level of pain after 10:56 AM and/or prior to discharge.
b. Review of the clinical record indicated that the patient arrived in same day surgery at

approximately 10:56 AM on 4/11/17, the patient had a BP of 94/54. The patient's BP at 11:55 AM was 91/58 and at 12:55 PM had a BP 77/45, pulse 73 and respirations 16. The nurse's note indicated that the patient was out of bed to the bathroom felt dizzy and faint, the physician was notified and 1 liter of lactated ringers was administered and blood pressure was rechecked at 1:55 PM and was 96/53. The clinical record indicated that the patient was discharged at 2:00 PM absent further rechecks of the patients blood pressure. The record failed to reflect the patients ambualtory status at discharge, pain level and/or that the patients BP was not +/- 20 Hq mm at discharge.

Interview with MD # 113 indicated that he was not aware of the patient's change in condition and/or low BP. MD #113 indicated that he would have kept the patient for more monitoring and would have drawn a blood count.

Review of the same day surgery criteria indicated that on discharge in part the patient's should have pain score at rest equal to or lower than 4, BP +/- 20 Hq mm of pre procedure range and ambulate with minimal assist.

c. Review of the ED record dated 4/11/17 at 8:03 PM identified that within 6 hours of discharge, Patient #107 arrived unresponsive with a systolic blood pressure of 80 per EMS and was 60/40 on arrival to the ED. After arrival to the ED, Patient #107 was responsive and complaining of abdoninal pain. Differential diagnoses included hemoperitoneum and small pneumoperitoneum is presumably post-operative rather than a perforated viscus. The patient required IV resuscitation, 2 units of blood, ICU monitoring, contition improved and was discharged on 4/15/17.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1) and/or (i) General (6).

21. Based on a review of clinical records, interviews, and policy and/or procedure checklists, for 2 of 2 patients reviewed for augmentation of labor, (Patient #160 and #157), the facility failed to ensure the Pre-Oxytocin checklist was completed prior to administration of Oxytocin. The findings include the following:

a. Review of the clinical record identified Patient #160 was admitted to the hospital on 11/18/18 with contractions at 41 weeks gestation. The History & Physical (H&P) dated 11/18/18 at 6:02 AM noted a category I (normal) fetal tracing was identified, cervix ripe per RN exam, and consider induction if strong, regular contractions do not recur spontaneously. A Physician's order dated 11/18/18 at 9:46 AM directed Oxytocin 30 units/500 milliliters in lactated ringers for the augmentation of labor and titrate per protocol B. At 9:58 AM, Oxytocin was administered at one (1) milliunit/minute intravenously, increased to 3 milliunits/minute at 10:30 AM, increased to 5 milliunits/minute at 11:00 AM, and then discontinued at 11:38 AM. The patient had a spontaneous vaginal delivery at 12:00 PM. Review of the Pre-Oxytocin checklist, the clinical record, and interview with the Nurse Manager on 11/19/18 at 2:00 PM failed to provide evidence that indication for induction was documented prior to the administration of Oxytocin, that the patient's pelvis was documented to be clinically adequate (should be on prenatal record), failed to document the estimated fetal weight within the past week, that general consent was signed, that the patient's cervix was assessed and documented immediately prior to induction (lack of

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documentation that a practitioner performed within four hours of induction), and/or that the presentation was assessed and documented. Review of the Pre-Oxytocin checklist directed that Oxytocin should not be initiated if the check list is incomplete.

b. Review of the clinical record identified Patient #157 was admitted to the hospital for induction of labor on 11/2/18 at 40 weeks and two days gestation. A Physician's order dated 11/2/18 at 8:30 AM directed Oxytocin 30 units/500 milliliters in lactated ringers for the augmentation of labor and titrate per protocol B. Review of the clinical record noted that Oxytocin was initiated at 9:19 AM and discontinued at 5:08 PM. A Physician's order dated 11/3/18 at 8:45 AM directed Oxytocin 30 units/500 milliliters in lactated ringers for the augmentation of labor and titrate per protocol B. Review of the clinical record dated 11/3/18 noted that Oxytocin was initiated at 9:56 AM and discontinued at 1:56 PM. Review of the Pre-Oxytocin checklist, the clinical record, and interview with the Nurse Manager on 11/19/18 at 2:00 PM failed to provide evidence that the patient's pelvis was documented to be clinically adequate.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical Records (2)(B) and/or (e) Nursing Service (1) and/or (i) General (6).

22. Based on a review of clinical records, interviews and policy review, for one sampled patient reviewed for magnesium sulfate administration, (Patient #159), the facility failed to ensure the patient was monitored in accordance with facility policy. The finding includes the following:

Patient #159 was admitted to the Labor & Delivery Unit of the hospital for observation on 6/19/18 at 6:00 PM with complaints of a gush of fluid at 32 weeks and 6 days gestation. Review of the H&P dated 6/20/18 at 12:22 AM identified that the patient had pregnancy induced hypertension and was noted with elevated blood pressures (BP). The plan of care included administration of steroids, antibiotics, and antihypertensive medication. A physician's note dated 6/23/18 at 12:22 AM identified that the patient's blood pressures were escalating, will proceed with induction of labor due to chronic hypertension with superimposed severe preeclampsia based on severe-range blood pressures, and administration of IV Magnesium Sulfate for seizure prophylaxis.

a. A physician's order dated 6/22/18 at 11:47 PM directed to administer Magnesium Sulfate 4 gram loading dose IV over 20 minutes. The Medication Administration Record (MAR) dated 6/23/18 noted the medication was administered from 12:30 AM until 12:50 AM. Review of the clinical record and interview with the Manager on 11/20/18 failed to identify that the patient's vital signs were monitored every five (5) minutes in accordance with facility policy. Review of the Magnesium Sulfate policy in Obstetrics directed that during the loading dose, the RN remains at the bedside and assesses BP, respiratory rate, heart rate and oxygen saturation every 5 minutes during the magnesium sulfate infusion.

A physician's order dated 6/23/18 at 8:58 AM directed to administer Magnesium Sulfate 2 grams maintenance dose at 75 ccs per hour. The Medication Administration Record (MAR) dated 6/23/18 noted the medication was administered from 12:50 AM through 9:24 AM. Review of the clinical record and interview with the Manager on 11/20/18

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failed to identify that vital signs were obtained per policy. Review of the Magnesium Sulfate policy in Obstetrics directed that during the maintenance dose, assess and document: BP, respiratory rate, heart rate and oxygen saturation every 15 minutes for first hour, every 30 minutes for second hour, then hourly.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (d) Medical Records (3) and/or (e) Nursing Service (1).

23. *Based on clinical record reviews, review of facility documentation and interviews for one of three sampled patients (Patient #2) reviewed for sequential compression sleeve monitoring, the facility failed to ensure documentation of assessments and/or monitoring of the sequential compression sleeves after placement and/or repositioning of the patient. The findings include:

a. Patient #2 was admitted to the same day surgery on 6/11/18 for a scheduled left shoulder arthroscopy surgery and the patient's past medical history included hypertension. Review of the clinical record identified between 9:27 AM to 9:38 AM the patient received a left shoulder Interscalene brachial plexus block administered by anesthesia for pain management. The clinical record identified the Operating Room (OR) table had been adapted with the T-Max shoulder positioner also known as Tenet positioning device for the procedure. The surgical case information notes identified Patient #2 was moved onto the OR table with assist of one and a pillow wedge was used to maintain a sitting position with the knees flexed, all pressure points were padded and the position was checked by MD. The notes further identified the sequential compression device (SCD) was applied to the bilateral lower legs at 45 pressure by RN #108. The intraoperative note identified the patient was in a supine position at 10:57 AM, intubated at 11:12 AM, placed in a beach chair position at 11:20 AM, the surgical incision was made at 11:48 AM and the patient was transferred to the recovery room at 2:24 PM. The nursing flowsheet PACU note on 6/11/18 at 2:26 PM, identified the bilateral pneumatic compression device on, vital signs stable and pain score 0 for pain assessment scale 0-10. The PACU note at 6:30 PM identified Patient #2 was complaining of bilateral lower extremity weakness below the knee and numbness to the feet. The significant event note dated 6/11/18 at 8:56 PM by the orthopedic Physician Assistant (PA) identified the patient was complaining of bilateral lower extremity paresthesia, there was no pain and no loss of motor distally, lumbar x-rays were ordered and the patient was admitted overnight for neuropathy. Subsequent nursing flowsheet notes at 10:45 PM identified the bilateral intermittent pneumatic compression device was on, the patient reported numbness, tingling, and decreased sensation, there were weak plantar and dorsi flexions and the MD aware. The neurology consult note dated 6/12/18 at 4:15 PM identified the patient with bilateral foot drop and dysesthesia from the straps on the legs per the patient causing tibial and peroneal neuropathies. The note identified the patient could not walk and the expectation was for the symptoms to improve over the next one to two (1-2) weeks. The note identified the recommendation was to discharge home with physical and occupational therapy, follow up in office in two (2) weeks and order Gabapentin if the symptoms worsen. The discharge summary dated

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6/13/18 identified Patient #2 was discharged home with diagnoses of left shoulder rotator cuff repair and acute bilateral tibial and peroneal neuropathies. Review of the clinical record failed to reflect documentation that assessments of the sequential compression sleeves after placement and after repositioning of the patient were completed. In addition, the clinical record failed to reflect that increased frequency of monitoring after the patient complained of bilateral lower extremity weakness along with continued use of the sequential compression device. In an interview on 11/15/18 at 9:10 AM, RN #108 identified the SCD sleeves are placed and turned on while the patient is awake and in the supine position. RN #108 stated for this procedure the head of bed is raised upright and the pillow wedge is placed under the legs after intubation. RN #108 identified the safety strap is secured across the patient's thighs and readjusted during reposition. RN #108 could not recall if an assessment of the bilateral lower extremities after initial placement of the SCD sleeves was conducted. In an interview on 11/14/18 at 12:15 PM, MD #110 identified the possible causes for Patient #2's bilateral foot drop, and tibial and peroneal neuropathy was compression on the peroneal area (located on the lateral fibula head) and the effect of straps on the lateral part of the leg. In an interview and clinical record review on 11/15/18 at 1:35 PM, the orthopedic Physician Assistant (PA #100) identified she assisted with Patient #2's surgery. PA#100 identified a safety strap was placed mid-thigh while the patient was in supine position, a pillow was placed and pushed up to the buttocks and under the patient's legs for positioning before the patient was repositioned into the beach chair position. PA #100 identified Patient #2 was of moderate size and sometimes the size of the patient's legs will cause external rotation. In an interview and record review on 11/19/18 at 11:40 AM, RN #111 identified she cannot recall details of the patient's complaining of leg discomfort but the standard practice is to check and document the placement of the compression sleeves before turning the SCD on. Review of the facility's sequential compression therapy standard of practice identified the sleeve should fit snugly but not tightly, check the fit by inserting two fingers between the sleeve and the patient's leg at the knee opening and to document application. In addition to assess the patient's skin under the sleeves at least every eight (8) hours to avoid skin breakdown, assess the extremities for peripheral pulses, edema, changes in sensation and movement at least once each shift. Review of the facility's patient positioning policy identified during and immediately after positioning to assess and maintain proper body alignment and tissue integrity. Reassessments are made following repositioning or any movement of the patient, bed or positioning devices.

<u>The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Staff (1).</u>

24. Based on review of the medical record and interviews for 1 (P#128) of 9 patients reviewed for pain management the hospital failed to ensure pain assessments were completed according to facility policy. The findings include:

a. Patient (P) #128 was evaluated in the Emergency Department (ED) on 11/8/18 for chief

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complaints of chest pain and chronic back pain.
During a review of the medical record with the ED Nurse Navigator, ED Manager and Registered Nurse (RN) #106 it was identified P#128 arrived in the ED at 2:35 AM. An initial triage nursing assessment completed at 2:50 AM and additional assessments between 2:52AM and 6:30 AM failed to identify P#128's pain assessment was completed. In addition according to the medical record P#128 received Ibuprofen and Tylenol for pain however the medical record failed to identify a pre and post pain score had been completed with the administration of the pain medications.
Hospital Pain Management policy indicated an initial assessment of pain was to be completed rating the severity numeric on a scale of zero to ten. In addition routine reassessment of pain is completed according to the routine schedule for vital signs.
Lippincott Procedures for Pain Management dated November 17, 2017 indicated the pain relief intervention used should be documented in addition to the patients rating of pain before and after pain management interventions.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical Staff (2)(B) and/or (d) Medical Records (3).

25. Based on clinical record review and staff interview for 1 of 3 sampled residents reviewed for medical record accuracy, (Patient # 15) the facility failed to accurately reflect a patients diagnoses. The findings include:

a. Patient # 15 was admitted to the hospitsl on 12/24/17. Review of the History and Physical dated 12/24/17 identified the patient had a diagnoses of type 2 Diabetes Mellitus. Review of the hospital discharge summary dated 1/5/18 identified Diabetes Mellitus type 2 as a discharge diagnosis. Interview with MD #114 on 11/19/18 2PM stated that the patient was not a diabetic and did not know how it got into the chart. MD # 114 stated that he would make a note in the chart to correct that.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical Staff (2)(B) and/or (d) Medical Records (3) and/or (e) Nursing Service (1).

26. Based on clinical record review, interview and policy review for one patient (Patient #107) the facility failed to ensure that a physician assessment was documented and failed to ensure that nurse documentation of patient blood pressures were documented accurately. The findings include the following:

a. Patient #107 was admitted on 4/11/17 for a laparoscopic cholecystectomy. A nursing pre-operative assessment identified a blood pressure of 129/76. A preoperative anesthesia assessment identified the patient's blood pressure as 129/72 at 7:15 AM. The patient arrived in PACU at 8:36 AM with a pain scale of 0/10 (10 worst) and a pain of 10/10 at 8:56 AM. Patient #107 received IV anxiolytic and pain medications. Pain at 9:35 was 4/10 and at 10:42 AM was 10/10.
Review of the anesthesia peripheral nerve block procedural note indicated that a TAP block was completed at 10:35 AM for post-operative analgesia. The anesthesia record identified the patient's blood pressure was 93/59, heart rate was 68, the patient was sedated, following

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commands, stable and tolerated the procedure well. Pain score was 3/10 post procedure at 10:46 AM.

Nursing notes dated 4/11/17 at 10:56 AM identified that Patient #107 was fully awake, out of bed to the bathroom, felt dizzy and faint, and had a blood pressure of 77/44. The physician was notified and 1 liter of lactated ringers was administered. A blood pressure recheck was 96/53. Patient stated he/she felt better with no further dizziness or feeling faint.

Review of nursing post-operative vital signs indicated that the patient's BP remained at "+/- 20 pre-op" or within 20mm Hg of pre-anesthetic systolic level for a high of 149 to a low of 109 at 10:00 and 10:56 despite documented blood pressures of 93/59 and 96/53 respectively.

According to a nurses note dated 4/11/17 at 10:48 AM a physician was in to assess the patient. However, the clinical record failed to reflect a documented assessment by the physician.

Patient #107 was discharged per post-anesthesia protocol at 2:00 PM with discharge instructions.

Interview with the Quality Specialist on 11/16/18 at 10:00 AM indicated that when the case was reviewed it was determined that the surgical resident was notified of the patients dropping blood pressure, saw the patient, ordered IV fluids and asked to be called after the fluids were administered however failed to write a note. Review of the medical staff bylaws indicated that progress notes content shall be sufficient information to permit continuity of care.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (d) Medical Records (3) and/or (e) Nursing Service (1).

27. Based on a review of clinical records, interviews and policy review, for one sampled patient reviewed for magnesium sulfate administration, (Patient #159), the facility failed to ensure the record accurately reflected the time frame in which the medication was administered. The finding includes the following:

a. Patient #159 was admitted to the Labor & Delivery Unit of the hospital for observation on 6/19/18 at 6:00 PM with complaints of a gush of fluid at 32 weeks and 6 days gestation.

Review of the H&P dated 6/20/18 at 12:22 AM identified that the patient had pregnancy induced hypertension and was noted with elevated blood pressures (BP). The plan of care included administration of steroids, antibiotics, and antihypertensive medication. A physician's note dated 6/23/18 at 12:22 AM identified that the patient's blood pressures were escalating, will proceed with induction of labor due to chronic hypertension with superimposed severe preeclampsia based on severe-range blood pressures, and administration of IV Magnesium Sulfate for seizure prophylaxis.

A physician's order dated 6/23/18 at 9:00 AM directed to administer Magnesium Sulfate 1 gram bolus over 60 minutes. Review of the MAR noted that the medication was administered during the period of 9:23 AM through 10:23 AM. Review of the flow sheets dated 6/23/18 at 9:24 AM identified that Magnesium Sulfate 3 g/hr. was administered at 75 ml/hr., a discrepancy compared to the MAR. Interview with the Manager on 11/20/18 at 3 PM stated this was an error in documentation and should reflect that the Magnesium Sulfate

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1 gram bolus was being administered on 6/23/18 from 9:23 AM through 10:23 AM.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (e) Nursing Service (1) and/or (g) Pharmacy and/or (i) General (6).

28. *Based on clinical record review, interview and policy review for one patient (Patient #6) the facility failed to ensure that medications were available for administration in a timely manner. The findings include the following:

a. Patient #106 presented to the ED on 1/23/18 at 5:00 PM with a past medical history of hyperthyroidism presented from a PCP office with complaints of shortness of breath, palpitations, nausea and vomiting. The patient had a productive cough with brown and blood tinged sputum. The note indicated that the patient had a history of hyperthyroidism and had been non-compliant with Methimazole (thyroid medication) for greater than one month. The patient was noted to have a new onset of atrial fibrillation in the setting of hyperthyroidism and poor medication compliance.

The ED note indicated that the patients Thyroid Stimulating Hormone (TSH) level was 0.0.

Pysician orders dated 1/23/18 at 11:42 PM directed to administer Methimazole 20 mg. A physician note dated 1/24/18 at 4:54 AM indicated Methimazole was unavailable and PTU 300 mg was ordered on 1/24/18 at 4:43 AM. The MAR indicated that the medication was administered at 1/24/18 at 4:58 AM. Review of the physician's note dated 1/24/18 at 4:54 AM indicated pharmacy contacted and Methimazole and PTU were not available. Several resources were activated to reveal a single dose of PTU was available in the ED and was administered to the patient.

Interview with RN # 110 on 11/19/18 at 11:30 AM indicated that when she assumed care of Patient #106 on 1/23/18 into 1/24/18, the Methimazole had been ordered (at 11:53 PM) but not yet given. RN #110 indicated that she was trying to get the medication and had called the pharmacist on-call because the pharmacy is closed at 12:00 AM. According to RN #110, the on-call pharmacist indicated that the medication was not available. RN # 110 indicated that she called the physician (approximately 4:43 AM) and notified her that the medication was unavailable and is was then that the physician ordered the PTU medication.

Interview with the Nurse Supervisor #100 indicated that she was not aware that the medication was unavailable. The Supervisor indicated that if she had been made aware, there is an online listing of all medications in house and where they are located. Nurse Supervisor #100 indicated that if a medication is unavailable a Pharmacist can be called in.

Review of the record with the Quality Coordinator failed to reflect a nurse's note related to the unavailability of the medication and/or the steps taken to obtain the medication between 1/23/18 at 11:42 and 1/24/18 at 4:43 AM.

Interview with the Assistant Pharmacy Director on 11/15/18 at 1:09 PM identified that telepharmacy services are available 24/7. On 1/24/18, Methimazole was available in the pharmacy and PTU was available in the emergency department. Since this incident, the hospital has increaced the availability of these medications.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (f)

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Diagnostic and therapeutic facilities and/or (i) General (6).

29. Based on document review, observations and/or interviews, the hospital failed to ensure that safety precautions were maintained and/or monitored for radiological services. The findings include:

a. The scope of the DEEP inspection was review St. Mary's Hospital's compliance with DEEP's Administrative Regulations Section 19-24-1 through 19-24-14 and the Regulations pertaining to the Center for Medicare/Medicaid Services (CMS).
The inspection consisted of observations, interview of hospital staff, an interview of the Chairman of the Radiation Safety Committee and a review of documents pertinent to the radiation protection program of St. Mary's Hospital.
Within the inspection the following violation was noted:
Section 19-24-8 of the DEEP's Administrative Regulations "Radiation Information Labeling" states:
Each area or room in which sources of ionizing radiation other than radioactive materials are used shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and appropriate wording to designate the nature of the source or sources of ionizing radiation (example below)
CAUTION *
X-RAY
Additionally, section 19-24-8 also states: CAUTION *
RADIATION AREA
This provision shall not apply to areas or rooms where x-ray equipment is used solely for diagnostic purposes by or under the direction of a healing arts practitioner as authorized by law"
Contrary to this, your CAT scan rooms which utilize X-Ray devices were posted "Caution Radiation Area" and one of the entrances to X-Ray room number one was not posted at all. It was noted this was corrected and all rooms inspected were properly posted by the completion of the inspection.
Additionally, Section 482.26 (b): "Standard Safety for Patients and Personnel" of the CMS Regulations states-"The radiologic services, particularly ionizing radiology procedures must be free from hazards for patients and personal". It continues with "Consistent with the requirements under the Quality Assessment and Performance Improvement (QAPI) CoP at 42 CFR 482.21, the hospital must monitor the quality and safety of radiological services."
Contrary to this, St. Mary's failed to comply with this standard in reference to performance of an annual radiation protection program audit.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (h) Dietary Service.

30. Based on observations, review of facility documentation and interviews, the facility failed to ensure opened food items were stored according to standards of practice. The findings include:

a. During tour of the kitchen with the Food Service Director on 11/19/18 it was identified on a

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wired shelve rack that multiple opened items were stored inappropriately, the following observations were made:
-an open packet of yellow cornmeal, the top was twisted and secured with plastic wrap fashioned into a tie closure, the manufacturer's expiration date was 12/15/18, there was no date to identify when the packet was opened.
-an open packet of cream based soup mix, dated 12/20, there was no manufacturer's expiration date, the top was loosely twisted with the contents exposed and plastic wrap was loosely fashioned into a tie closure.
-an open packet Italian Farro grain with no date to identify when the packet was opened, the manufacturer's expiration date was 1/18/19, the top of the packet was loosely twisted with the contents exposed, and plastic wrap was loosely fashioned into a tie closure.
-an open packet of batter tempura mix, the top was rolled and folded, there was no date to identify when the packet was opened, and there was no manufacturer's expiration date.
-an open packet of Thai chili sauce mix, the top was rolled and folded, there was no date to identify when the packet was opened, there was no manufacturer's expiration date, and the packet had food stains.
-an open packet of whole wheat flour with the top rolled and folded, there was no date to identify when the packet was opened, and there was no manufacturer's expiration date.
-an open packet of powdered instant non-fat dry milk, the top was loosely twisted, there was no date to identify when the packet was opened, and there was no manufacturer's expiration date.
Upon surveyor inquiry the identified items were removed and discarded.
In an interview on 11/19/18, the Director of Food Services identified it was expected that all food items are dated when opened and that the manufacturer expiration date which is either found on the item or on the box the items were delivered in is followed. The Director of Food Services stated if there was a question regarding the expiration date, it is expected that staff follow the shelf life guidelines.
Review of the Food Product Shelf Guidelines identified in part, that opened non-fat dry milk should be stored in an airtight container for three (3) months, cornmeal should be kept tightly closed in dry storage for eighteen (18) months, whole wheat flour kept in dry storage for six (6) months and sauce mixes kept in storage for six (6) to twelve (12) months.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (6) and/or (l) Infection Control.

31. Based on clinical record review, interview and policy review the facility failed to ensure that infection control techniques were utilized. The findings include the following:
Tour and observation in the Cardiac Catherization lab was completed on 11/13/18 during the period of 9:30 AM through 10:00 AM.

a. Observation of staff in Room 2 identified two staff members whose hair covering failed to encompass all of their hair. Review of the policy indicated surgical head covers or hood thatcover all scalp skin and hair will be worn.
b. Observation 11/13/18 at 9:45 AM identified RN #102 with gloves on prepping the patients left groin area. The RN removed her gloves and went to the supply cart and

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obtained new gloves failing to perform hand hygiene after glove removal. RN #102 donned clean gloves returned to the table, removed a drape, discarded the drape, remove gloves and proceed to the computer then to the medication delivery system failing to perform hand hygiene.

c. RN #103 was observed on 11/13/18 at 9:55 AM in the cath lab without gloves on pick up a wrapper off the floor and discard it, and failed to perform hand hygiene after. Review of the facility policy indicated perioperative staff will perform hand hygiene before entering the invasive procedure room. The policy indicated all personnel moving within or around a sterile field will do so in a manner that prevents contamination of the sterile field.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (e) Nursing Service (1) and/or (i) General (6) and/or (l) Infection Control.

32. Based on observations and interviews, the facility failed to ensure an Intravenous (IV) irrigation bag was stored according to the standards of practice. The findings include:

a. During tour of the Operating Room (OR) department on 11/8/18, it was identified in OR Room #4 (the urology procedure room) that a three (3) liter irrigation bag of normal saline was hanging in a pressurized device without the benefit of an outer cover. Upon surveyor inquiry, it was identified that the OR room was not used earlier nor was there a procedure scheduled for that day 11/8/18. In an interview with the Infection Control Nurse (ICN) it was identified that the outer cover of an IV bag should remain in place until ready for use.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical Staff (2)(B) and/or (i) General (6).

33. *Based on observations, facility documentation and interviews for one of three glucometers, the facility failed to ensure the glucometer was disinfected according to manufacturer's recommendation and/or that infection control recommendation was implemented. The findings include:

a. During tour of the Operating Room (OR) department and surveyor inquiry on 11/8/18, it was identified that the glucometer in the main OR was not disinfected according to the manufacturer's directions. In an interview on 11/8/18, ORA #1 identified he/she cleans the glucose meter with alcohol wipes. In an interview on 11/8/18, the Infection Control Nurse identified bleach wipes are available and should be used to disinfect the glucose meter. Review of the Glucose Meter basic operating and maintenance information policy identified in part, to clean the outside of the meter with an approved disinfectant cloth after each patient use.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6).

34. *Based on a review of clinical records, facility documentation, interviews, and policy review, for one of three patients reviewed for vena cava filter removal (Patient #124),

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the hospital failed to ensure that the catheter was removed in its entirety. The finding includes:

a. Review of Patient #124's clinical record identified that the patient signed informed consent on 5/19/17 at 2:40 PM for the removal of the inferior vena cava (IVC) filter with associated risks that included bleeding and/or infection.
Review of the operative report authored by MD #116, dated 6/13/17, identified that the patient had the IVC filter removed under ultrasound-guidance. The needle, instrument, and sponge counts were correct at the end of the case and the patient tolerated the procedure well. The total fluoro time was not documented in the operative record.
Although the post-operative note reflected that MD #114 (Interventional Radiologist) was consulted intraoperatively for assistance, the operative note failed to note why the IR physician was consulted. Review of MD #114's note dated 6/13/17 identified that MD #116 requested assistance during the procedure. Using fluoroscopic assistance, a 4 French glide catheter was used through the indwelling right internal jugular access sheath to advance the glide wire from the superior vena cava (SVC) to the IVC (inferior vena cava), after which the glide catheter was advanced over the wire into the IVC and from this point MD #116 completed the procedure and MD #114 left the operating room.
On 6/13/17 at 11:29 AM, MD #117 (Resident) directed th epatient to have a chest x-ray to rule out pneumothorax with a subsequent order at 12:20 PM, may discharge home, x-ray read by MD #117 (Resident).
Review of the chest x-ray result dated 6/13/17 at 11:43 AM identified coiled radiopaque density right infrahilar region, which may represent a retained foreign body, less likely an overlying structure although may be confirmed with PA and lateral views. No appreciable consolidation or pneumothorax. Results called to MD #116. This report was authenticated by a radiologist on 6/13/17 at 1:00 PM.
Review of a chest CT dated 6/13/17 at 4:51 PM noted opaque foreign body, likely retained products from the IVC filter removal, within the right lower lobe vessels, likely within the pulmonary artery.
Review of the interventional radiology (IR) procedure note dated 6/15/17 at 5:35 PM identified that MD #115 noted that the patient had the IVC filter removed intraoperatively on 6/13/17 with subsequent imaging that demonstrated a large foreign body in the right pulmonary artery. The foreign body retrieved appeared to be a 37 centimeter (cm) long stretched catheter fragment that was sent to pathology.
Review of the pathology report dated 6/16/17 identified that the foreign body was that of soft pliable catheter measuring 37 cm and appears to show partial diameter segment of the catheter of unknown original diameter.
Record review and interview with MD #116 on 11/20/18 at 11:30 AM stated the filter was noted to be tipped on the venogram and he was having difficulty therefore requested the assistance of an interventional radiology physician. MD #116 stated MD #114 went inside his snare, already in place, with a smaller one then MD #116 was able to retrieve the filter. MD #116 stated that although he inspected the catheter after the procedure, it was "hair like to the naked eye and appeared ok" and was unsure if the retained catheter was the one he used or the one MD #114 used during the procedure.
Record review and interview with MD #115 on 11/20/18 at 1:30 PM stated although he was

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

not present during the retrieval of the filter on 6/13/17, it was his opinion that the snare utilized during the procedure may have been too large and sheared the catheter.
Record review and interview with the Quality Manager on 11/20/18 at 3PM stated that MD #117 noted that the patient did not have a pneumothorax and subsequently discharged the patient on 6/13/17, however, failed to identify the retained foreign body. The Manager stated that it was the Radiologist who noted the retained foreign body after the patient left the hospital and was called back for an additional x-ray and chest CT to confirm the retained foreign body.
Review of the corrective action plan (CAP) with the Quality Manager stated the hospital was unable to determine when and/or why the piece of the glide catheter fractured because the main piece of the glide catheter was disposed of prior to the investigation. Subsequent to this incident, all IVF filter removals will take place in the interventional radiology department by an interventional radiologist. The CAP was verified as implemented during the onsite visits.
Review of the Prevention of Retained Surgical Items policy directed staff to take measures to prevent intravascular device (catheter, guidewire, sheath) fragments by the following, in part, insert and remove intravascular devices in accordance with the manufacturer's IFU, inspect devices before use to identify defects, do not withdraw catheters and guidewires through a needle (if the catheter or guidewire is replaced, withdraw it simultaneously with the needle), account for the device in their entirety by inspecting for breakage immediately on removal from the patient.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6).

35. *Based on clinical record review and policy review the facility failed to ensure that for 1 of 2 patients (Patient #130) on a ventilator that the clinical record reflected the rationale for a change in the ventilator settings. The findings include the following:

a. Patient #130 was admitted on 11/7/18 with shortness of breath, pneumonia, acute respiratory distress syndrome, and congestive heart failure. The record indicated that on 11/8/18 at 3:00 AM the patient was intubated. Review of the physician's orders dated 11/8/18 order at 5:01 AM directed an assist control, FiO2 of 80, PEEP of 10 and titrate FiO2 to keep saturations above 92%. The order dated 11/8/18 at 5:39 AM directed a FiO2 of 80 and titrate FiO2 to keep saturations above 92%. Review of the RT documentation indicated that on 11/8/18 at 5:30 the patient vent was set with a PEEP of 8 and FiO2 of 70 %, the failed to reflect that the vent was set based on the physician orders.
Review of the Oxygen Saturations with RT #100 indicated that on 11/8/18 at 5:00 AM the patient's oxygen saturation was 97%, 92% at 5:30 AM and at 6:00 AM. The record failed to reflect the rationale for the titration of the FiO2 to 70% in relation to failing to meet physician direction to maintain a saturation of greater than 92%.
Interview with RT #100 on 11/8/18 at 10:40 AM indicated that there should be a RT note

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for the rationale for the titration of the FiO2. RT #100 indicated that she increased the patients FiO2 at the beginning of her shift secondary to the patient "breathing too fast" and a saturation of 91%.

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2)(B) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6).

36. *Based on clinical record review, interview and policy review the facility failed to ensure that for one of three patients (Patient #23) having a bronchoscopy that medications were administered based on a physician's order and/or per manufacturer's recommendations. The findings include the following:

a. Patient #123 presented to the ED 0n 5/19/17 with general weakness. Review of the critical care H&P dated 6/1/17 at 1:22 PM indicated that the patient had a history of breast cancer, chronic obstructive lung disease. The patient had a bronchoscopy on 6/1/18, review of the record indicated that at 9:35 AM, 2% Lidocaine was not available and 20% benzocaine 1 second spray was administered times three. The record failed to reflect the presence of an order for the 20% benzocaine and/or the 2% Lidocaine. Interview with RT #101 on 11/15/18 at 10:00 AM indicated that she was not aware of the correct dose and administered two sprays and then chencked for a gag reflex and since the patient had a gag reflex administered one more spray.
b. Review of the physician's procedural note dated 6/1/17 indicated that 2% Lidocaine topical solution 3 cc's was administered before the procedure. The record failed to reflect that the respiratory therapist notified the physician of the medication not being available. Interview with the Quality Manager on 11/15/18 at 9:00 AM indicated there was no policy and/or protocol to support the practice of RT administered the medication absent a physcians order.
c. In addition review of the manufacturer's direction for use indicated that ½ second of spray should be administered with the ability to repeat times one. The MDU directed that the recommended dose not be exceeded.
The note indicated that at 11:05 AM the procedure was completed, the patient had a saturation of 91% on a 50% venti mask. At 11:40 AM the patient desaturated to 69-70 % paced on 15 liters, 100 mg of methylene blue was administered.